

REMARKS

Upon entry of this amendment, claims 1-5, 9-14, and 128 are pending in the instant application. Claims 1 and 128 have been amended. Claims 6 and 137 have been cancelled, and Applicants reserve the right to prosecute that subject matter, as well as the originally presented claims, in continuing applications. The amendments presented herein are fully supported by the specification and claims as originally filed. For example, support for the amendments to claims 1 and 128 is found at least in Example 3, Example 4 and in Figure 17b. Accordingly, no new matter has been added by the amendments presented herein.

I. Claim Amendments

The Examiner has indicated that the amendments to claims 3 and 4 made in the amendments filed on October 15, 2004 and reproduced on pages 16-17 in Applicants' Appeal Brief do not comply with the requirements of 37 C.F.R. § 1.121(c). In particular, the Examiner has indicated that the October 15, 2004 listing of claims does not include the term "between" in line 2 of claims 3 and 4.

The term "between" was inadvertently omitted from line 2 of claims 3 and 4 in the listing of claims presented in conjunction with Applicant's October 15, 2004 response. The term "between" has been included in the listing of claims presented herein. Accordingly, Applicants submit that the listing of claims presented herein complies with the requirements of 37 C.F.R. § 1.121(c).

II. Claim Rejections Under 35 U.S.C. § 103

Claims 1-5, 9-14, 128 and 137 have been rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,834,186 by George *et al.* ("George") in view of U.S. Patent No. 6,630,306 by Breaker *et al.* ("Breaker") and King, "Post-Translational Modifications", April 12, 2000 ("King"). According to the Examiner, the George reference describes "regulatable polynucleotides having a catalytic domain that is linked to a ligand binding sequence, placing the activity of the catalytic domain under the control of that ligand and requiring the presence of the ligand for activation or inactivation." In addition, the Examiner has indicated that the Breaker reference describes "allosterically modified DNazymes that can be preferentially regulated by

peptides that are 9 amino acids or less”, while the King reference describes post-translational phosphorylation of proteins to regulation the biological activity of the protein. The Examiner has concluded that “it would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the teachings of George *et al.* with the teachings of Breaker in the design of the instant invention.” (Office Action, pages 3-4).

Applicants note that claim 6 was not rejected under 35 U.S.C. § 103 over George in view of Breaker and King. The pending claims have been amended herein to incorporate the subject matter of claim 6 into amended independent claim 1 (and consequently, claims 2-5 and 9-14, which depend therefrom) and into independent claim 128. Claim 137 has been cancelled herein, thereby obviating the rejection as it pertains to this claim. Accordingly, Applicants submit that the pending claims, as amended herein, are not obvious in view of the George, Breaker and King references. As such, this rejection should be withdrawn.

IV. Claim Rejections Under 35 U.S.C. § 102

The Examiner has rejected claims 1-5, 9-11, 13 and 137 under 35 U.S.C. §102(e) as being anticipated by the Breaker reference (U.S. Patent No. 6,630,306)). In particular, the Examiner has asserted that Breaker describes “the isolation of DNA polynucleotides comprising an allosteric site and an enzyme domain spatially distinct from said allosteric site, wherein reversible interaction of a chemical effector with the allosteric site on the DNA polynucleotide reversibly alters the cleavage function or configuration of the DNA polynucleotide.” (Office Action, page 6).

Applicants note independent claims 1 and 128 have been amended herein, and claim 137 has been cancelled. As amended, independent claim 1 (and claims 2-5, 9-11 and 13 which depend therefrom) recites a DNA polynucleotide that is regulated by a peptide effector comprising a regulatable, catalytically active polynucleotide having a catalytic domain and a regulatory domain, wherein the catalytic activity of the catalytic domain is regulated by the interaction of the peptide effector with the regulatory domain, wherein the catalytic activity is ligation, and wherein the DNA polynucleotide comprises the sequence 5’-
GGACCUCGGCGAAAGC-N50-GAGGUUAGGUGCCUCGUGAUGUCCAGUCGC -3’,
where N is any nucleotide. Amended claim 128 is directed to a vector comprising a regulatable,

catalytically active, DNA polynucleotide having a catalytic domain and a regulatory domain, wherein the catalytic activity of the catalytic domain is regulated by the interaction of a peptide effector with the regulatory domain, wherein the catalytic activity is ligation, and wherein the DNA polynucleotide comprises the sequence 5'- GGACCUCGGCGAAAGC-N50-GAGGUUAGGUGCCUCGUGAUGUCCAGUCGC -3', where N is any nucleotide.

In contrast to the polynucleotides of the claimed invention, the Breaker reference does not teach the isolation of DNA polynucleotides that include a catalytic domain and a regulatory domain under the control of a peptide effector, wherein the catalytic activity of the catalytic domain is ligation and wherein the DNA polynucleotide comprises the sequence 5'- GGACCUCGGCGAAAGC-N50-GAGGUUAGGUGCCUCGUGAUGUCCAGUCGC -3', where N is any nucleotide. As the Breaker reference does not disclose every element of the claimed invention, this reference cannot destroy the novelty of the claimed polynucleotides. Accordingly, Applicants request that the Examiner withdraw this rejection.

V. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claim 6 under 35 U.S.C. §112, first paragraph for lack of written description. According to the Examiner, "neither the prior art nor the specification as filed provides an adequate description of the peptide effector regulated DNA ligase as set forth in instant claim 6." (Office Action, page 8).

As described above, the pending claims have been amended herein to recite catalytic DNA polynucleotides that include the sequence 5'- GGACCUCGGCGAAAGC-N50-GAGGUUAGGUGCCUCGUGAUGUCCAGUCGC -3', where N is any nucleotide, wherein the catalytic activity of the polynucleotide is ligation, and wherein the ligation activity is regulated by the interaction of a peptide effector with the regulatory domain of the polynucleotide. The pending claims are also directed to vectors containing these catalytic DNA polynucleotides.

Such regulatable, catalytic nucleic acids (RCANAs), as well as methods for isolating these RCANAs, are described throughout the as-filed specification, *e.g.*, in Example 3, Example 4 and in Figure 17b. Thus, the as-filed specification provides a detailed description of the method for identifying peptide-dependent ligase RCANAs, as well as the actual reduction to practice of three distinct peptide-dependent ligase RCANAs, including disclosure of clone


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sequences, a drawing of the predicted secondary structure, physical and chemical properties, and functional data. Accordingly, Applicants submit that the as-filed specification demonstrates that Applicants were in possession of the claimed invention at the time the instant application was filed. Applicants, therefore, respectfully request that the Examiner withdraw this rejection.

CONCLUSION

On the basis of the foregoing amendments, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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